

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, October 27, 2008, 1:00 pm – 2:00 pm ET

Minutes

I. Welcome and Introductions - call participants (listed alphabetically):

- David Brown, Colgate Palmolive Company
- Jeffrey Karp, Geronmed, Inc.
- Maureen Kapustynski, Cadbury
- Mike Koenig, U.S. Food and Drug Administration
- Juris Lazdins Novartis Consumer Health, Inc.
- Paula Markert, GlaxoSmithKline Consumer Healthcare (co-leader)
- Andras Megyeri, Novartis Consumer Health, Inc.
- Kathryn Moreng, Bayer Consumer HealthCare
- Paulette Midgett, Johnson & Johnson•Merck Consumer Pharmaceuticals Co.
- Janet Riffitts, McNeil Consumer Healthcare
- Barbara Spallitta, Reckitt Benckiser, Inc.
- Siobhan Stevens-Miles, Merck & Co., Inc.
- Ranga Velagaleti, BASF Corporation
- Ann Vu, U.S. Food and Drug Administration
- Marcia Howard, CHPA staff (sub-team liaison)

II. Standing Teleconference Date and Time

The next teleconference will be November 10, 2008, at 1:00 pm ET unless cancelled.

III. Draft Guidance

FDA issued an industry draft guidance on October 23, 2008, Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing. Complete information is available at:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-25338.pdf>. Sub-team members are asked to determine if a submission on behalf of the group is needed. Comments may also be developed by the SPL Drug Listing and Electronic Registration (DL/ER) sub-team.

IV. SPL OTC sub-team Q&A Document/Wiki Page

The Q&A document has been placed on the OTC sub-team [Wiki page](#). The goal is to have a static document available for reference along with a “living” version for group discussion. Each question and comment from the static document will be given its own discussion page on the OTC sub-team Wiki page to accept feedback, responses, etc. This procedure will allow for an historical record of the discussion to be maintained. New questions and comments should be emailed to sub-team leaders Paula Markert (GSK) and Devon Morgan (Perrigo), and Marcia Howard (CHPA, sub-team liaison) to post to the site (*i.e.*, please do not initiate a new discussion page). On matters for which a definitive answer can be and is obtained, the answer will be posted along with appropriate references.

Sub-team members are encouraged to continue sending their questions for posting and to visit the Wiki discussion pages.

V. Educational Opportunities

DIA In-person SPL Workshop (October 29-30, 2008, in Philadelphia, PA). Please visit [CHPA website](#) for additional information, including registration materials.

The list of OTC panel discussion questions sent to DIA in advance will be forwarded to the sub-team [completed October 28, 2008]. Attendees will also have an opportunity to pose questions live or on question cards at the event. SPL OTC sub-team members, who will be in Philadelphia on Tuesday evening and wish to assemble for an informal dinner, should meet in the lobby of the Sheraton between 8:00-8:30 pm ET.

VI. Other

There was a brief discussion on issues facing sub-team members, such as questions about DUNS numbers and difficulty using some of the SPL forms, which could not be answered during the call. Maureen Kapustynski (Cadbury) agreed to forward her question (regarding DUNS numbers and corporate locations) to Lonnie Smith and communicate the response back to the sub-team.

VII. Next Steps and Assignments

- A. Marcia Howard (CHPA) will circulate the Q&A DIA panel questions to sub-team members along with the recently released draft guidance on electronic registration and drug listing. [Sent Tuesday, October 28, 2008.]
- B. Sub-team members should continue to email questions for the Q&A document and visit the Wiki pages for discussion of the issues between the teleconferences.

MDH/10-28-08

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Last Revised: November 4, 2008 Sent: November 4, 2008